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### **REMARKS**

In the Office action, the Examiner rejected Claims 1-12 and 16-30 under 35 U.S.C. §102(b) as being anticipated by Burns (U.S. 4,624,253). The Applicant has carefully reviewed the Burns reference and respectfully notes the following differences between the teachings of Burns and the Applicant's claimed invention.

The subject application is directed to a disposable lancet device for piercing human skin. It comprises a lancet housing and a lancet body displaceably supported by the housing, with a piercing tip of the lancet body concealed within the housing in a rest position of the body. An operating device ("an operator" in Claim 1) that is integral with or connected to the lancet body is provided for manually displacing the lancet body from its rest position to expose the piercing tip. The movement of the operator and lancet body from the rest position is against a return or biasing device whereby the lancet body is automatically retracted to its rest position when the manual displacement force is removed from the operator. The operator is then readily manually separable from the lancet body to prevent subsequent manual displacement of the lancet body from its rest position, such as after use where the piercing tip is bloodied. Thus, the manual separation of the operator from the lancet body occurs after successful use of the lancet device to prevent a subsequent use, at the discretion of the user, so as to reduce unintentional transfer of blood components.

However the lancet device of the Applicant's invention can also be reused by a single user, either in the home or by a person administering the incision, so that a first attempt can be repeated if it does not succeed. However, the Applicant's device can also be disabled permanently to prevent reuse (page 2, third paragraph), and this feature is entirely missing from the Burns '253 reference.

In the Burns reference, the lancet assembly 10 has a lancet holder guide housing 12 and a lancet holder body 16 displaceably supported by the housing having a lancet holder 26 holding a lancet blade 30 such that the blade 30 is concealed within the housing in a rest position of the body. A top 18 acting as a push button is integral with the lancet holder body 16 for manually displacing the lancet body to expose the lancet blade, and a return coil spring 34 against which

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the lancet body operates as it is manually displaced to expose the lancet blade 30 whereby the spring automatically retracts the lancet body to its rest position when the manual displacement force is removed from the operator. However, the top 18 is neither adapted to be disengaged nor readily manually separable from the lancet holder body 16 after use to prevent subsequent manual displacement of the lancet body from its rest position. Thus Burns fails to teach "... the operator is readily manually separable from the lancet body after use ..." (Claim 1 as currently amended) nor "... an actuator operating the lancet body between the concealed and an operational positions wherein the piercing tip is exposed and wherein the actuator can repeatedly change between the concealed and operational positions and wherein the actuator is also disableable so as to inhibit further achievement of the operational position ..." (Claim 25 as previously presented). Thus, the Applicant believes Claim 1 as currently amended and Claim 25 as previously presented as well as the Claims depending therefrom are novel and patentable under the requirements of 35 U.S.C. §102(b) over the teaching of Burns '253.

The Examiner also rejected Claims 1-12 and 14-30 under 35 U.S.C. §102(b) as being anticipated by the Schraga reference (U.S. 5,908,434) The Applicants have carefully reviewed the Schraga '434 reference and respectfully note that the lancet device of Schraga is also not designed to be disabled after use to prevent subsequent manual displacement of the lancet body from its rest position. Furthermore, the lancet device of Schraga is of a fundamentally different design to that of the applicant's invention, in that it is actuated by spring loading. Therefore, in addition to the device in US 5908434 not having an operator that is readily manually separable from the lancet body after use, it also does not have an operator integral with or connected to the lancet body for manually displacing the lancet body to expose the piercing tip. Instead, the Schraga device operates as follows.

The device in US 5908434 is primed by using the exterior head 72 to manually lift the lancet receiving assembly 40 and lancet 30 onto the engagement hub 50 of the actuation assembly 60. The lifting is by means of the cocking elements 74 engaging the abutments 48, and the hooks 47 of the retention members 45 of the lancet receiving assembly then engage on the enlarged head 52 of the engagement hub 50 in a snap-engaging manner. The lifting of the lancet receiving assembly 40 is against the bias of spring 44, which preloads the lancet assembly. To

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release the lancet assembly, the actuation head 62 is pressed to separate the retention members 45 and release them from the enlarged head 52 of the engagement hub 50. The force of the spring drives the lancet piercing tip 32 out through the opening 37 in the cover 35 to pierce the skin. The piercing tip 32 is withdrawn back into the cover 35 by means of retraction assembly 49, at which stage the device is in the fired condition shown in Figure 2. The cycle may then be repeated.

Although the operator (actuation assembly 60) is separable from the lancet body (retraction assembly 49) in US 5908434, this is not a manual separation and the separation is not "after use to prevent subsequent manual displacement of the lancet body from its rest position" (Claim 1 as currently amended) nor "disableable so as to inhibit further achievement of the operational position" (Claim 25 as previously presented). Thus, the Applicant believes Claim 1 as currently amended and Claim 25 as previously presented as well as the Claims depending therefrom are novel and patentable under the requirements of 35 U.S.C. §102(b) over the teaching of Schraga '434.

The Examiner also argues that US 5611809 to Marshall et al. discloses a lancet body disposed within a lancet housing and an operator engaged with the lancet body which is breakable from the lancet body. This is correct. However, we disagree with the Examiner's contention that the subject matter of Claims 1, 12 and 13 are lacking novelty under the requirements of 35 U.S.C. § 102(b) in the light of this reference.

In particular, the device of US 5611809 has a lancet body 3 with a piercing tip 18 displaceably supported by the housing against the bias of a spring 4. An operator 10 is actuatable for manually displacing the lancet body to expose the piercing tip through the action of an engagement pin 16. The pin 16 is connected to the actuator 10 through a thin web 17, but merely abuts the lancet body 3. Thus, the operator 10 is neither "integral with or connected to the lancet body", as required by Claim 1 nor does Marshall et al. disclose a lancet device "wherein the actuator can repeatedly change between the concealed and operational positions" (Claim 25 as previously presented).

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When the Marshall et al. operator 10 is manually actuated, it acts through the pin 16 to displace the lancet body to the condition shown in Figure 2. In this condition, the lancet body is fully displaced, but the operator 10 can still be displaced further. This occurs with additional force applied to the operator 10, which breaks the web 17. This condition is shown in Figure 3 in the '809 patent, where the operator 10 has moved fully forwardly, but the lancet body has been retracted under the action of the spring 4 and the pin 16 has correspondingly moved rearwardly with the lancet body and relative to the operator 10. Claim 1 is therefore further distinguished from the disclosure in US 5611809 by the fact that the return (spring) does not automatically retract the lancet body to its rest position when the manual displacement force is removed from the operator. Instead, the lancet device in the '809 patent is designed for the return spring to automatically retract the lancet body to its rest position when additional manual displacement force is applied to the operator and the web 17 is broken. Furthermore, it is not possible for the operator to be readily manually separated from the lancet body after use. Instead, the separation occurs when additional manual displacement forces applied to the operator causes the web 17 between the operator 10 and pin 16 to be broken.

There are several consequences of the above distinctions between US 5611809 and the Applicant's invention. In the Applicant's invention the lancet device can be reused additional times as needed at the discretion of the user since separating the operator from the lancet body is an entirely manual function. Furthermore, once the separation has occurred, it is readily apparent that the lancet device cannot be used again because the operator has been separated from the lancet body. In contrast, in US 5611809, once the lancet device is used properly once, it cannot be reused. However, it is not possible to tell whether or not the driving connection between the operator 10 and the lancet body 3 has been broken, without actually displacing the operator. If the operator 10 is displaced to test whether or not the web 17 has been broken, the lancet piercing tip 18 will be exposed if the web 17 has not been broken, with substantial risk of accidental needlestick injury. This is exactly the risk that the lancet device of the Applicant's invention is intended to avoid.

There is a suggestion at column 3, lines 23 to 35 that the shearable web 17 could be between the pin 16 and the lancet body 3, instead of between the pin 16 and the operator 10.

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However, all of the above comments still apply. Furthermore, there is a suggestion that the firing pin 16 can be dispensed with altogether. However, there is no illustration or enabling written description of how this would be effected. Furthermore, there is still no suggestion of the operator being adapted to be disengaged from or readily manually separable from the lancet body after use to prevent subsequent manual displacement of the lancet body from its rest position. Thus, the Applicant believes Claim 1 as currently amended as well as the Claims depending therefrom including Claims 12 and 13, are novel and patentable under the requirements of 35 U.S.C. §102(b) over the teaching of Marshall et al. '809.

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### SUMMARY

From the foregoing, the Applicant believes that the claimed invention is novel and patentable under the requirements of 35 U.S.C. § 102(b) over the teachings of Burns '253, Schraga '434, and Marshall et al. '809. The Applicant believes that the application is in a condition ready for allowance and respectfully requests prompt issuance of a Notice of Allowability. The Applicant believes that this paper is fully responsive to the rejections made by the Examiner in the Office Action, however should there remain any further impediments to the allowance of this application that might be resolved by a telephone conference, the Examiner is respectfully requested to contact the Applicant's undersigned representative at the indicated telephone number. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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